K081910

SEP 1 7 2008

510 (k) Summary

As Required by 21 section 807.92 (c)

1. **Submitter Name:** Siam Sempermed Corp., Ltd
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5. **Contract Person:** Mrs. Parawan Paiyasan (Quality System Manager)
6. **Date summary prepared:** June 20, 2008
7. **Official Correspondent:** Sempermed USA Inc.
8. **Address:** 13900 49th Street North
   Clearwater, USA , FL 33762
9. **Phone:** 727 787 7250
10. **Fax:** 727 787 7558
11. **Contact person:** Mr. William E. Harris
12. **Device Trade or Proprietary Name:** Non-sterile, powdered latex examination gloves.
13. **Device Common or usual name:** Examination glove
14. **Device Classification Name:** Glove , Patient Examination , Latex
15. **Description of the Device:**
Non-Sterile, powdered latex examination gloves.
16. **Intended use of the device:**
This device is a disposable device intended for medical purpose that is worn on the examiner 's hand to prevent contamination between patient and examiner.
17. **Summary of The Technological Characteristics of The devices :**
Non-Sterile, powdered latex examination gloves are summarized with the following technological characteristics compared to ASTM or equivalent standards.

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE
Dimensions	ASTM D 3578-05	Meets
Physical Properties	ASTM D 3578-05	Meets
Freedom from pinholes	ASTM D 3578-05	Meets
Powdered Residue	ASTM D 3578-05	Meets
Protein Level	ASTM D 3578-05	Meets
Biocompatability	Primary Skin Irritation in Rabbits	Passes
	Guinea Pig Sensitization	Passes

18. Substantial Equivalents Based on Assessment of Non-Clinical Performance Data

The performance test data of the non-clinical tests that support a determination of substantial equivalence is the same as mentioned immediately above.

19. Conclusion

It can be concluded that Non-Sterile, powdered latex examination gloves will perform according to the glove performance standards referenced in section 17 above and meet ASTM standards, and FDA requirements. Consequently, this device is substantially equivalent to currently marketed devices.This device is safe and effective as the predicate device *Siam Sempermed Latex Examination Glove , Powdered.* Indeed , it is equivalent This is better expressed in the tabulated comparison as below.

Technical comparison of specific elements is attached in the main submission.

FDA file reference number	510k number: K895642
Attachments inside notification submission file	REFER TO APPENDIX 1
TECHNOLOGICAL CHARACTERISTICS	*Comparison result* **REFER TO ADDITIONAL TECHNICAL COMPARATIVE TABLE WITHIN 510K SUBMISSION**
Indications for use	Identical
Target population	Identical
Design	Identical
Materials	Identical
Performance	Identical
Sterility	Not applicable
Biocompatibility	Identical
Mechanical safety	Identical
Chemical safety	Identical
Anatomical sites	Identical
Human factors	Identical
Energy used and/or delivered	Identical (Not applicable)
Compatibility with environment and other devices	Identical
Where used	Identical
Standards met	Identical
Electrical safety	Identical (Not applicable)
Thermal safety	Identical (Not applicable)
Radiation safety	Identical (Not applicable)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 7 2008

Siam Sempermed Corporation, Limited
C/O Mr. John Calhoun
Manager of Regulatory Affairs
Sempermed USA, Incorporated
13900 49th Street North
Clearwater, Florida 33762

Re: K081910
Trade/Device Name: Non-Sterile, Powdered Latex Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYY
Dated: August 26, 2008
Received: August 29, 2008

Dear Mr. Calhoun:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Non-Sterile, Powdered Latex Examination Gloves

Indications For Use: A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Prescription Use _____ AND/OR Over-The-Counter Use ✓
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K 081940